

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND **TOXIC SUBSTANCES**

December 03, 2001

MEMORANDUM:

Subject:

Efficacy Review of "EPA Reg. No. 63838-01 "BioSide™ HS 5%"

Case No. 064697

DP Barcode: D277169

From:

Bruce H. Mann

Efficacy Evaluation Team Product Science Branch

Antimicrobials Division (7510C)

To:

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Thru:

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Applicant:

Enviro Tech Chemical Services, Inc.

PO Box577470 Modesto, CA 95357

Formulation From Label:

Active Ingredient(s)	% by wt
Peroxyacetic acid	4.90
Hydrogen peroxide	
Inert Ingredient(s)	68.60
Total	100.00

V. Results

MRID Number	Organism	Numbers Control		Numbers of Reduction	
		CFU	Log ₁₀	CFU	Log ₁₀
454582-01	Listeria monocytogenes	8.4 x 10 ⁷	7.92	8.4 x 10 ⁷	7.92
(30 seconds)		<10	0	<10	0
Log reduction		>7.92	>7.92	>7.92	>7.92
454582-02	Salmonella choleraesuis	9.7 x 10 ⁷	7.99	9.7 x 10 ⁷	7.99
(30 seconds)		<10	0	<10	0
Log reduction		>7.99	>7.99	>7.99	>7.99
454582-03	Staphylococcus aureus	8.16 x 10 ⁷	7.91	8.16 x 10 ⁷	7.91
(30 seconds)		7.91	0.60	2.1 x 10	1.36
Log reduction		7.31	7.31	6.55	6.55
454582-03	Escherichia coli	8.18 x 10 ⁷	7.91	8.18 x 10 ⁷	7.91
(30 seconds)		1.30 x 10	1.11	4.00 x 10	0.60
Log reduction		6.80	6.80	7.31	7.31
454582-03 (30 seconds) Log reduction	Escherichia coli	Lot #10111 8.18 x 10 ⁷ 4.0 x 10 ⁰ 7.31	Lot # 10111 7.91 0.60 7.31	Killed > 99.999% (for all test samples)	Killed >99.999% (for all test samples)
454582-03 (30 seconds) Log reduction	Staphylococcus aureus	Lot #10111 8.18 x 10 ⁷ <10 >7.91	Lot #10111 <10 0 >7.91	Killed > 99.999% (for all test samples)	Killed > 99.999% (for all test samples)

VI. Conclusions

- 1. The submitted sanitizing efficacy data are supportive of the product's effectiveness as a sanitizer for precleaned food contact surfaces against *Listeria monocytogenes* ATCC #984 in the presence of 400 ppm of synthetic hard water (AOAC) for previously cleaned hard nonporous surfaces when thoroughly wetted and allowed to remain wet for an exposure time of 60 seconds at a temperature of 20°C and at a use dilution of 1.50 ounce/5 gallons (1:426.70) (MRID #454582-01).
- 2. The submitted sanitizing efficacy data are supportive of the product effectiveness as a sanitizer for precleaned food contact surfaces against Salmonella choleraesuis ATCC 10708 in the presence of 400 ppm synthetic hard water (AOAC) for previously cleaned hard nonporous surfaces when thoroughly wetted and when allowed to remain wet for an exposure time of 30 seconds at a temperature of 20°C at a use dilution of 1.50 ounce/5 gallons (1:426.70) (MRID #454582-02).
 - 3. The submitted sanitizing efficacy data are also supportive of the product's

effectiveness as a sanitizer for precleaned food contact surfaces against *Staphylococcus* aureus ATCC #6538 and *Escherichia coli* ATCC #11229 in the presence of 400 ppm synthetic hard water (AOAC) for previously cleaned hard nonporous surfaces when thoroughly wetted and when allowed to remain wet for an exposure time of 30 seconds at a temperature of 20°C at a use dilution of 1 ounce/5 gallons (MRID #454582-03).

VII. Recommendations

1. Under the directions for use, on the bottom of page #2, under "sanitizing food contact surfaces", revise the use dilution of 1 ounce of BioSide™ HS 5% dissolved in 5 gallons of water (0.16%v/v concentration) to read "1.50 ounce of Bioside™ HS 5% dissolved in 5 gallons of water (0.23% concentration v/v concentration). This revision is also applicable under directions for use on page #3. This revision is applicable for the proposed label pinpunched 05-21-2001.